UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

FRIEDA AARON., *et al.*,	:	Case No. **1:13-cv-301** (lead case)
	:	1:13-cv-202
Plaintiffs,	:	1:13-cv-214
	:	1:14-cv-325
	:	1:14-cv-483
	:	
	:	
	:	Judge Timothy S. Black
v.	:	
	:	
MEDTRONIC, INC., *et al.*,	:	
	:	
Defendants.	:	

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS (Doc. 61)

This civil action is before the Court upon Defendants' motion to dismiss the Omnibus Complaint filed August 28, 2015 (Doc. 61). The Omnibus Complaint (Doc. 54) consolidates the claims from five cases brought against Defendants. *See* 4/20/15 Minute Entry and Notation Order. Plaintiffs filed a response to the motion to dismiss on October 26, 2015 (Doc. 63), and Defendants filed a reply on December 15, 2015 (Doc. 65).

I. BACKGROUND

Defendants Medtronic, Inc. and Medtronic Sofamor Danek, USA, Inc. (hereinafter referred to collectively as the singular "Medtronic") are medical device manufacturers. Medtronic manufactures many products, but the product at the center of this case is called Infuse. Infuse is used to stimulate bone growth in spinal fusion surgeries.

Infuse, like all medical devices sold in the United States, is regulated by the Food and Drug Administration (FDA), which draws its regulatory authority in this area from

the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA). 21 U.S.C. § 360c *et seq.* Under the MDA, different types of devices receive different levels of FDA scrutiny. Devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk . . . of injury" are designated "Class III" devices. 21 U.S.C. §360c(a)(1)(C)(ii). Infuse has been classified as a Class III medical device by the FDA. Class III devices like Infuse "incur the FDA's strictest regulation" and must receive Premarket Approval (PMA) from the FDA before being sold. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001).

"Premarket Approval is a 'rigorous' process." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). To obtain PMA, a manufacturer "must submit a detailed PMA application" that contains, among other things, "specimens for the proposed labeling of the device." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006), *aff'd*, 552 U.S. 312 (2008). The FDA closely scrutinizes PMA applications, "weigh[ing] any probable benefit to health from the use of the device against any risk of injury or illness from such use." *Riegel*, 552 U.S. at 318 (quotation marks omitted). "The FDA spends an average of 1,200 hours reviewing each application" and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* If the FDA decides that the device's proposed design, manufacturing methods, or labeling is inadequate, the FDA can require revisions prior to approval. *Id.* at 319.

"Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or

effectiveness. § 360e(d)(6)(A)(i)." *Id.* A manufacturer which wishes to make such changes "must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR § 814.39(c)." *Id.*

Infuse is one component of a medical device that was granted PMA by the FDA in 2002. The device itself consists of a collagen carrier sponge soaked with liquid protein rhBMP–2 (this is the portion of the device referred to by the parties and by this Order as "Infuse") and a metallic cage, the LT–Cage. (Doc. 54, at 86–87). The protein-soaked sponge is placed inside the LT–Cage which is inserted into the patient's spine. (*Id.*, at 87). The premarket approval specifies that the FDA-approved Infuse device consists of all component parts which must be used together. (*Id.* at 92). The Infuse device was approved only for use in a single-level fusion in the L4–S1 region of the lumbar spine via the Anterior Lumbar Interbody Fusion procedure and in combination with the LT–Cage. (*Id.* at 92–93). Use of the device in a manner not approved by the FDA is considered an "off-label" use. (*Id.* at 92). Nevertheless, medical practitioners are not prohibited from using a legally marketed device like Infuse in a manner that has not been approved by the FDA. *See* 21 U.S.C. §396*; Buckman,* 531 U.S. at 341.

Plaintiffs in this case are several hundred former patients of Dr. Atiq Durrani, M.D., an orthopedic surgeon operating in the Cincinnati area (in the past). The Omnibus Complaint alleges that Dr. Durrani either directly performed or ordered surgeries utilizing Infuse on Plaintiffs. The Complaint further alleges that each surgery was done using Infuse in a manner that was "off-label," meaning that Infuse was not used in the specific

manner for which the FDA gave PMA to the device. Specifically, Plaintiffs allege that they were subjected to the following off-label uses of Infuse:

> [s]ome of the Omnibus Plaintiffs were implanted with Infuse® without the LT–Cage. Some were subjected to a posterior surgical approach. Others had Infuse® implanted in multiple levels of the spine. And some Omnibus Plaintiffs had Infuse® implanted in their cervical or thoracic spines.

(Doc. 63, at 9–10). Plaintiffs further allege that, as a result of off-label use of Infuse, each Plaintiff has suffered injury.

The Omnibus Complaint raises the following claims against Medtronic on behalf of all Plaintiffs:

(1) fraudulent concealment, misrepresentation and fraud in the inducement;

(2) strict products liability (failure to warn);

(3) strict products liability (design defect);

(4) strict products liability (misrepresentation);

(5) products liability (negligence); and

(6) breach of express and implied warranties.

II. STANDARD OF REVIEW

A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) operates to test the sufficiency of the complaint and permits dismissal of a complaint for "failure to state a claim upon which relief can be granted." To show grounds for relief, Fed. R. Civ. P. 8(a) requires that the complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief."

While Rule 8 of the Federal Rules of Civil Procedure "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). Pleadings offering mere "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id*. (citing *Twombly*, 550 U.S. at 555). In fact, in determining a motion to dismiss, "courts 'are not bound to accept as true a legal conclusion couched as a factual allegation[.]'" *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265 (1986)). Further, "[f]actual allegations must be enough to raise a right to relief above the speculative level[.]" *Id*.

Accordingly, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678. A claim is plausible where "plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. Plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id*. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief,'" and the case shall be dismissed. *Id*. (citing Fed. Rule Civ. P. 8(a)(2))

III. ARGUMENT

A. Pleading Standards

An important issue argued by both parties, and relevant to all of Plaintiff's claims, is with what specificity these claims must be pleaded.

Generally, pleadings are governed by Rule 8 of the Federal Rules of Civil Procedure, which states in relevant part:

> A pleading that states a claim for relief must contain:
>
> (1) a short and plain statement of the grounds for the court's jurisdiction, unless the court already has jurisdiction and the claim needs no new jurisdictional support;
>
> (2) a short and plaint statement of the claim showing that the pleader is entitled to relief; and
>
> (3) a demand for the relief sought, which may include relief in the alternative or different types of relief.

Fed. R. Civ. P. 8(a).

As previously stated above, Federal Rule of Civil Procedure 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Thus, Defendants argue that:

> Conclusory allegations that the defendant violated FDA regulations in the manufacture, labeling, or marketing of the premarket approved medical device are insufficient to state a parallel state-law claim and thereby avoid preemption under § 360k(a)." *Ali v. Allergan USA, Inc.*, 2012 WL 3692396, at *6 (E.D. Va. 2012). Thus, "Plaintiffs cannot simply incant the magic words 'Medtronic violated FDA regulations' in order to avoid preemption." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), *aff'd sub nom. Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010); *accord, e.g., Caplinger I*, 921 F. Supp. 2d at 1224. Rather, "to avoid preemption, Plaintiff must sufficiently allege a 'parallel' claim in accordance with general pleading standards." *Franklin*

> *v. Medtronic, Inc.*, 2010 WL 2543579, at *8 (D. Colo. 2010), *report and recommendation adopted*, 2010 WL 2543570 (D. Colo. 2010). "To state a 'parallel' claim" that escapes preemption under § 360k(a), "a plaintiff must allege … the violation of a *specific* federal requirement." *Millman*, 2015 WL 778779, at *4 n.2 (emphasis added); *accord, e.g., Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300–01 (11th Cir. 2011). Moreover, "'[t]o properly allege parallel claims, the complaint must set forth *facts*'" that, if true, would establish the predicate federal violation. *Franklin*, 2010 WL 2543579, at *8 (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008)) (emphasis by court).

(Doc. 65, at 36–37).

Plaintiffs admit that, for several of the claims in the Omnibus Complaint, Plaintiffs did not plead specific federal laws nor regulations that were allegedly violated. (*See* Doc. 63, at 28). However, Plaintiffs argue that the specific circumstances behind a medical device products liability case merit a more permissive review of a Complaint's Rule 8 compliance. Thus, Plaintiffs ague that:

> The better reasoned analysis regarding the specificity required in the context of a design defect claim (or any other claim) and MDA preemption is that a plaintiff need not identify the precise defect or the specific federal regulatory requirements that were alleged violated in order to comply with Rule 8. *Waltenburg v. St. Jude Medical, Inc.*, 33 F. Supp.3d 818, 827 (W.D. Ky. 2014). The Walternberg [sic] Court relied upon the following quote from the Court of Appeals for the Seventh Circuit in *Bausch v. Stryker Corp.*, 630 F.3d at 560 (7th Cir. 2010):
>
> > Defendants object that the original complaint does not specify the precise defect or the specific federal regulatory requirements that were allegedly violated. Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6). *Id.*
>
> The Seventh Circuit based its decision in part on the fact that "in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law [and] there is no public access to complete versions of [the FDA's premarket approval] documents." *Id.*

> Thus, the *Bausch* Court reasoned that "[i]f plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion." *Id.* at 561. *See also Garross v. Medtronic, Inc.*, 77 F. Supp.3d 809, 817 (E.D. Wis. 2015).

(*Id.* at 28 fn. 8).

Several courts have disagreed with *Bausch*'s holding that particularity was not required in a products liability pleading involving FDA Class III medical devices. *See, e.g., Bertini v. Smith & Nephew, Inc.*, 2013 WL 6332684, at *4 (E.D.N.Y. 2013); *Ali v. Allergen USA, Inc.*, 2012 WL 3692396, at *14 (E.D. Va. 2012). While the Sixth Circuit has not directly addressed the holding in *Bausch*, it did recently reject the notion that Rule 8's pleading standards should be lowered in circumstances where there was a natural imbalance of information, stating that to survive a motion to dismiss, a "plaintiff must allege specific facts . . . even if those facts are only within the head or hands of the defendants." *New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011). That ruling has been applied in the medical device context by a recent ruling within this district that articulately summarized the issue:

> Plaintiffs seem to contend that their complaint should be allowed to proceed because they can't get to the facts that would support their causes of action without discovery (doc. 8, "it is impossible for Plaintiff to be certain how the [medical device] injured her because there has not yet been discovery"). Unfortunately for Plaintiffs, discovery cannot be used as a fishing expedition to uncover the facts necessary to support the causes of action presented in the complaint, "even when the information needed to establish a claim . . . is solely within the purview of the defendant or a third party." *New Albany Tractor, Inc., v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir.2011). Plaintiffs "may not use the discovery process to obtain facts after filing suit." *Id.* Absent factual support from which the Court may plausibly infer negligence, Count One fails to meet the pleading

> standard set forth by the Supreme Court in *Iqbal* and *Twombly* and must therefore be dismissed.

Anderson v. Boston Scientific Corp., 2013 WL 632379 (S.D. Ohio 2013). Application of such an analysis is also appropriate in this case, and this Court finds that Plaintiffs' claims must meet the pleading standards of Rule 8 as defined in *Iqbal* and *Twombly* in order to survive a motion to dismiss.

Furthermore, even were the Court to apply the lowered pleading standard from *Bausch*, several of Plaintiffs' claims would still be deficient because they are not adequately pleaded even under that standard. Here, "unlike [the plaintiffs in *Bausch*], Plaintiffs simply do not allege—or provide any factual support for an allegation of—violations of federal law" with respect to several of their claims. *Id.* at *4 fn. 1 (dismissing a products liability claim as insufficiently pleaded to be a parallel claim allowed by the MDA).

B. Plaintiffs' State Law Claims and Causes of Action Are Preempted by Federal Law

1. Express Preemption

The MDA's preemption clause, 21 U.S.C. § 360k(a), prohibits the use of state law to enforce any requirement that is "different from, or in addition to" requirements imposed by the FDA. Congress adopted § 360k(a) as a "general prohibition on non-Federal regulation" of medical devices to ensure "that innovations in medical device technology are not stifled by unnecessary restrictions" and to protect device manufacturers from the "undu[e] burdens" of "differing requirements . . . imposed by

jurisdictions other than the Federal government." H.R. Rep. No. 94-853, at 12, 45. The MDA thus "swept back some state obligations and imposed a regime of detailed federal oversight," enforced by an expert federal agency rather than by private plaintiffs and lay juries applying state tort law. *Riegel*, 552 U.S. at 316.

Although preemption of state-law tort claims may leave some injured individuals "without . . . judicial recourse," Congress determined that the loss to those comparatively few individuals was outweighed by the benefit to the far greater number "who would suffer without new medical devices if juries were allowed to apply the tort law of 50 states to all innovations." *Riegel*, 552 U.S. at 326; *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1346 (10th Cir. 2015) ("Any additional state duties on top of those already imposed by federal law, even if nominally limited to off-label uses, might check innovation, postpone access to life-saving devices, and impose barriers to entry without sufficient offsetting safety gains."). As an alternative to private tort suits, Congress granted the FDA extensive authority to police device manufacturers under deferral law. *See Buckman*, 531 U.S. at 349.

However, not all state law claims involving medical devices are preempted by the MDA. The Supreme Court has explicitly held that "[n]othing in [21 U.S.C.] § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). With this holding, the Supreme Court has recognized that it cannot be an abrogation of federal supremacy for a state to impose restrictions on medical devices that are already imposed by the FDA; only by imposing different or

additional requirements to those imposed by federal regulations can a state common-law claim be preempted by the MDA.

Accordingly, 21 U.S.C. § 360k(a) creates a two-step test for determining whether state-law claims are preempted. *See, e.g.*, *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300–01 (11th Cir. 2011); *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Thorn v. Medtronic Sofamor Danek, USA, Inc. et al.*, 81 F. Supp. 3d 619, 623–24 (W.D. Mich. 2015). First, a court must determine whether "the Federal Government has established requirements applicable to" the medical device. *Riegel*, 552 U.S. at 321. If the Federal Government has, the court must then determine whether the state-law claims impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements. *Id.* at 322; *Hafer et al. v. Medtronic Inc., et al.*, 99 F. Supp. 3d 844, 855–56 (W.D. Tenn. 2015).

a. Established Federal Requirements

Plaintiffs argue that their state-law claims are not preempted because the FDA has not established any requirements for Infuse as it was used on the Plaintiffs in this case. This claim is without merit.

The crux of Plaintiffs' argument is that the product that was used on each of the Plaintiffs, Infuse, was only one component of the medical device that received PMA from the FDA, and that the FDA therefore did not impose any requirements upon Infuse itself:

> The device that received PMA approval from the FDA was a combination device consisting of two components—the Infuse® bone protein and the LT-Cage. The LT-Cage™ is an intervertebral spacer cage that must be used in combination with the bone protein. The FDA's 2002 approval of Medtronic's PMA for this device was expressly restricted to the use of both

> components together: "These components must be used as a system. The InFuse™ Bone Graft component must not be used without the LT-CAGE™ Lumbar Tapered Fusion Component." These are not merely requirements the FDA is imposing on an approved device. **This is the FDA's definition of the device it approved.**

(Doc. 63, at 19 (emphasis in original)).

Plaintiffs' argument that the FDA has not established federal requirements for Infuse's rhBMP-2 component when used without the LT-Cage component is incorrect. Premarket approval extends to all components of an approved device, even when a physician uses the components separately. Thus, nearly every court to consider this issue in an Infuse case has held that "premarket approval is as controlling of the individual components . . . as it is to the device as a whole." *Hawkins v. Medtronic, Inc.*, 2014 WL 346622, at *5 (E.D. Cal. 2014).[1] Courts addressing other devices have likewise held that claims arising from use of a particular component of a device are "also subject to PMA preemption." *Smith v. Depuy Orthopedics Inc.*, 552 F. App'x 192, 196 (3d Cir. 2014).[2] There is therefore no doubt that § 360k(a) applies here.

Plaintiffs cite two cases to support the proposition that § 360k(a) does not impose FDA requirements on the individual components of an approved medical device.

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[1] *Accord, e.g., Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 858 (W.D. Tenn. 2015); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1032–33 (D. Haw. 2014); *Ledet v. Medtronic, Inc.*, 2013 WL 6858858, at *3 (S.D. Miss. 2013); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1176 (C.D. Cal. 2013); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *11–12 (E.D. La. 2013); *Latimer v. Medtronic, Inc.*, 2015 WL 5222644, at *7 (Ga. Super. Ct. 2015)

[2] *Accord, e.g., Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 251–55 (E.D.N.Y. 2014); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 487 (W.D. Pa. 2012); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009); *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 471 (D. Mass. 2012).

The first case, *Samet v. Procter & Gamble Co.*, 2013 WL 3124647 (N.D. Cal. 2013), deals with food packaging as regulated by the FDCA, not medical devices. Although 21 U.S.C. §360k(a) is discussed by the court in *Samet*, it is not directly bearing upon the case, and the court's ruling in that case contains no discussion of whether the FDA's regulating a system of components establishes requirements on the individual components themselves.

Plaintiffs' other cited case, *Purchase v. Advanced Bionics, LLC*, 896 F.Supp.2d 694 (W.D. Tenn. 2011), is also not analogous to the present case. In *Purchase*, the defendant manufacturer modified a Class III medical device that had received PMA by replacing one component that had gone through the approval process with an entirely separate component that did not go through that process. *Id.* at 697. In the present case, third parties (such as Dr. Durrani) used one component of an approved medical device either in a manner that was not approved by the FDA or without using the complete device. In *Purchase*, a component that had not undergone FDA scrutiny was being used in procedures on patients; in this case, Infuse *has* been subjected to that scrutiny, and is subject to the same regulations as the complete device itself.

Several courts throughout the country have examined this exact issue and have held that "the FDA established specific federal requirements for the Infuse Device, even when the Infuse Protein is used alone." *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 412 (Minn. Ct. App. 2015); *accord, e.g.*, *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1176 (C.D. Cal. 2013) (rejecting "Plaintiff['s] argu[ment] that the PMA process for the Infuse Device only establishes federal requirements for the InFUSE Bone Graft used in

conjunction with the LT–Cage, but not the InFUSE Bone Graft used alone"); *see also, e.g.*, *Hafer*, 99 F. Supp. 3d at 858 ("the PMA does impose federal requirements upon the BMP/Sponge"); *Beavers-Gabriel*, 15 F. Supp. 3d at 1033 ("[E]ven though off-label use of only a component of the Infuse Device is at issue, the FDA approval applies 'with respect to' the Infuse Device generally and therefore such approval includes its components.").

Indeed, Plaintiffs' assertion that premarket approval of the Infuse device does not extend to the device's constituent components cannot be reconciled with the FDCA, which explicitly defines "[t]he term 'device'" to "includ[e] *any component*" of a device. 21 U.S.C. § 321(h) (emphasis added). *See also Angeles*, 863 N.W.2d at 411 ("The FDCA's definition of 'device' includes 'any component, part, or accessory.'") (quoting 21 U.S.C. § 321(h)); *accord Hafer*, 99 F. Supp. 3d at 858. Thus, "[t]here is no merit to Plaintiff[s'] assertion that § 360k(a) does not apply because Plaintiff[s'] surgeon[s] supposedly implanted the Infuse device without its LT-Cage component." *Latimer*, 2015 WL 5222644, at *7.

The FDA's granting of PMA to the Infuse protein and LT-Cage medical device concomitantly established federal requirements on Infuse alone.

b. Parallel Claims

As the FDA's granting of PMA to the Infuse medical device created federal requirements applicable to the device, Plaintiff's state law claims can survive only if the requirements imposed by the state laws are parallel to those imposed by the FDA. Any state-law requirement imposed on FDA-regulated medical devices that is "different from,

or in addition to" FDA requirements is expressly preempted and cannot support a Complaint. 21 U.S.C. § 360k(a).

1) Failure to Warn

Plaintiffs' Omnibus Complaint alleges that Medtronic is liable for Plaintiffs' injuries due to Plaintiffs' failure to warn of the dangers of Infuse. Specifically, the Complaint states:

> At all relevant times, Defendants misrepresented the safety of Infuse® to physicians and spine patients, including to Plaintiffs and Dr. Durrani, and recklessly, willfully, or intentionally failed to inform each Plaintiff and Dr. Durrani of the significant dangers to patients resulting from the off-label use of Infuse®.
>
> Any warnings Defendants may have issued concerning the dangers of off-label uses of Infuse® or regarding the specific risks of those uses were insufficient in light of Defendants' contradictory prior, contemporaneous, and continuing illegal promotional efforts and promotion of Infuse® for non-FDA-approved off-label uses in the spine and Defendants' contemporaneous efforts to hide or downplay the true risks and dangers of the off-label uses of Infuse®.

(Doc. 54, at 82).

Plaintiffs' failure to warn claims are expressly preempted by 21 U.S.C. § 360k(a). First and most obviously, to the extent that Plaintiffs allege that Defendants were required to give any warning other than those that were required by the FDA as part of its PMA of Infuse, those claims are expressly denied as being inconsistent with federal law. 21 U.S.C. § 360k(a).

Plaintiffs argue that "the failure to warn claim is premised upon Medtronic's failure to file adverse-event reports with the FDA." (Doc. 63, at 26). The FDA requires that all manufacturers or importers of medical devices "shall report[] whenever the

manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices . . . may have caused or contributed to a death or serious injury." 21 U.S.C. § 360i(a)(1). Plaintiffs claim that Ohio's duty to warn extends to third parties, which in this case would include the FDA. Ohio's imposition of a duty to warn would therefore be a parallel requirement as it pertains to warning the FDA, because federal law already requires that a device manufacturer do so in the form of adverse-event reports.

Plaintiffs' argument is without merit. Although federal law requires device manufacturers to report certain adverse events to the FDA, there is no state-law duty to report adverse events to the FDA. And the federal duty *to report certain information to the FDA* is not "identical" (*Lohr*, 518 U.S. at 495), and thus not parallel, to the state-law duty *to provide warnings to patients or their physicians*. *See McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1199–1200 (M.D. Fla. 2013); *McClelland v. Medtronic, Inc.*, 2012 WL 5077401, at *6 (M.D. Fla. 2012). Because the state-law duty to warn is "not genuinely equivalent to a duty imposed by the FDCA" (*Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013)), Plaintiffs' "allegations that Medtronic failed to report adverse events to the FDA do not state a parallel claim." (*Cales v. Medtronic Inc.*, 2014 WL 6600018, at *10 (Ky. Cir. Ct. 2014)). Doctors are warned of the risks associated with a medical device through the device's labeling, not through adverse-event reports submitted to the FDA.

Adverse-event reports are not warnings. Although the FDA "*may* disclose" adverse-event reports, it is not required to do so. 21 C.F.R. § 803.9(a) (emphasis added).

Thus, adverse-event reports, unlike the warnings on a device label, "are not automatically made public." *Pinsonneault*, 953 F. Supp. 2d at 1016; *accord Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1286 (N.D. Ga. 2014) ("[T]he FDA's disclosure of [adverse-event reports] to the public is not guaranteed").

Furthermore, adverse-event reports do not necessarily result in labeling changes and cannot be used by a manufacturer to unilaterally change the label. Labeling changes require FDA approval (*see* 21 C.F.R. § 814.39), and the FDA may not approve a safety-related labeling change absent "valid scientific evidence" (*id.* § 814.20(b)(3)(vi)), a category that specifically excludes "[i]solated case reports" and "reports lacking sufficient details to permit scientific evaluation" (*id.* § 860.7(c)(2)). Because adverse-event reports are anecdotal and "do[] not necessarily reflect a conclusion by . . . FDA . . . that the device . . . caused or contributed to the reportable event" (FDA, *Manufacturer and User Facility Device Experience Database*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm), adverse-event reports are not by themselves sufficient grounds for a labeling change. Given that adverse-event reports are regulatory submissions, not warnings, that must be submitted to the FDA, not to patients or their physicians, the federal duty to submit adverse-event reports to the FDA is "not genuinely equivalent" to a state-law duty to warn physicians, and thus cannot support a failure-to-warn claim, even if allegedly violated. *Pinsonneault*, 953 F. Supp. 2d at 1016.

Moreover, because the FDCA does not require that a manufacturer furnish adverse-event reports directly to physicians, any state-law requirement that a

manufacturer do so is "different from, or in addition to, any requirement applicable under the FDCA and its implementing regulations, and is pre-empted." *Pinsonneault*, 953 F. Supp. 2d at 1016; *see also Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) ("[a]ny claim, under state law, . . . that Defendant failed to warn patients beyond warnings required by the FDA" is expressly preempted by § 360k(a)).

There is, conversely, no state-law requirement that medical-device manufacturers submit adverse-event reports to the FDA. Plaintiffs' Omnibus Complaint does not identify any Ohio (or other state) authority that "recognize[s] a state common-law failure-to-warn claim based on a failure to properly issue reports to a federal agency, such as the FDA." *Pinsonneault*, 953 F. Supp. 2d at 1015. Thus, a "state law duty to warn the [patient] or her physician" does not parallel "manufacturer reporting requirements to the FDA." *McClelland*, 2012 WL 5077401, at *6. Accordingly, an alleged failure to submit adverse-event reports to the FDA cannot support a state-law failure-to-warn claim. *See Pinsonneault*, 953 F. Supp. 2d at 1016; *Cales*, 2014 WL 6600018, at *10; *Lake v. Kardjian*, 874 N.Y.S.2d 751, 755 (Sup. Ct. 2008) ("[T]he alleged failure … to comply with the MDA's reporting requirements does not constitute a 'parallel claim.'"); *cf. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011) ("State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA").

Plaintiff has provided the Court with cases in other circuits in which state-law failure-to-warn claims against medical device manufacturers were permitted to proceed based on the theory that the defendants' failure to provide adverse-event reports to the FDA was a violation of parallel state and federal requirements on manufacturers. *See*

Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013) (*en banc*), *cert. denied*, 134 S. Ct. 2839 (2014); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011). However, this Court finds that the requirements imposed by Ohio state law and the FDA's adverse-event report rule are not parallel. This Court agrees with the many courts cited by Defendants which have held that the requirement to file adverse-event reports with the FDA is not parallel to state products liability law regarding failure to warn.

Accordingly, Plaintiffs' failure to warn claims are expressly preempted under 21 U.S.C. § 360k(a) and are therefore dismissed.

2) Design Defect Claim

Plaintiffs have also raised a design defect claim against Defendants. Specifically, the Omnibus Complaint alleges:

> Defendants' Infuse® device was defectively designed at the time that it left their control and was placed into the stream of commerce. The device reached each Plaintiff without a substantial change in the condition in which it was sold.
>
> Defendants' Infuse® device was defectively designed because the design was unsafe when used in the manner promoted by Defendants and/or in a manner reasonably foreseeable by them. The Infuse® product failed to perform as safely as an ordinary consumer would expect when used, as it was promoted by Defendants and their agent, Dr. Durrani, for an off-label manner in spine surgeries.
>
> Defendants' Infuse® device was defectively designed because the risks of danger in the design outweigh the benefits of the design.
>
> The Infuse® product was designed in a way that caused users to suffer injuries including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than equally-effective, alternative designs and treatments.
> The foreseeable risks of harm posed by using the Infuse® product in a manner promoted by Defendants and their agent, Dr. Durrani, could have

> been reduced or avoided by adopting a reasonably alternative design. Defendants did not adopt a design that would have rendered the Infuse® product reasonably safe.

(Doc. 51, at 802–03).

Plaintiff's design defect claim is expressly preempted by 21 U.S.C. § 360k(a). Notably, the Omnibus Complaint does not allege, even in a conclusory fashion, that the design of the Infuse device Plaintiffs received was anything other than the design approved by the FDA through the PMA process. Thus, "to prevail on this claim, Plaintiffs would need to establish that the Infuse Device should have been designed in a manner *different* than that approved by the FDA." *Beavers-Gabriel*, 15 F. Supp. 3d at 1040 (emphasis added).[3]

However, the Supreme Court's decision in *Riegel*—which held that § 360k(a) preempts "claims of strict liability . . . and negligence in the design" of a device (552 U.S. at 320)—squarely forecloses any such claim, which would necessarily "establish design requirements different from, or in addition to, federal requirements for the Infuse Device." *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1222 (W.D. Okla. 2013). Indeed, a state-law claim that would require a medical device to have a design different from that approved by the FDA through the PMA process is a frontal "attack[] on the risk/benefit analysis that led the FDA to approve" the device. *In re Medtronic*, 623 F.3d

[3] *Accord, e.g.*, *Byrnes v. Small*, 60 F. Supp. 3d 1289, 1298 (M.D. Fla. 2015); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 989 (E.D. Mo. 2014); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 707 (S.D. Tex. 2014); *Angeles*, 863 N.W.2d at 420.

at 1206.[4] Accordingly, "this is the exact type of claim that is expressly preempted under § 360k(a)." *Caplinger*, 921 F. Supp. 2d at 1222.

Plaintiffs' response argues that, although there were no specific allegations that Defendants manufactured Infuse contrary to FDA specifications in the Complaint, the design defect claim should still be allowed to proceed. The response lists several statutes, unmentioned in the Omnibus Complaint, that "may have been violated by Medtronic." (Doc. 63, at 28–30). However, many of these statutes are irrelevant, and several of them are statutes regulating *manufacturing* defects rather than *design* defects. Even read in the manner most possibly favorable to Plaintiffs, the Omnibus Complaint cannot be said to allege manufacturing defects (*i.e.*, that the Infuse used in Plaintiffs' surgeries was not produced according to FDA specifications); only design defects (*i.e.*, that the process for manufacturing Infuse that was approved by the FDA is faulty) are properly alleged. However, allowing a design defect claim to proceed would be tantamount to holding that a medical device design that has been approved by the FDA can nonetheless be legally deficient—an encroachment on federal regulatory authority that 21 U.S.C. § 360(k) was specifically designed to prevent.

Accordingly, Plaintiffs' design defect claims are preempted and therefore warrant dismissal.

[4] *Accord, e.g.*, *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 219 (6th Cir. 2000); *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1044 (D. Ariz. 2014); *Houston*, 957 F. Supp. 2d at 1177; *Kashani–Matts v. Medtronic, Inc*, 2013 WL 6147032, at *4 (C.D. Cal. 2013).

3) Breach of Express Warranty

Count Six of Plaintiffs' Omnibus Complaint alleges that Medtronic breached purported express warranties with respect to the "effectiveness [and] safety" of the Infuse device and the "absence of complications" associated with its use. (Doc. 54, at 810–11). For Plaintiffs to prevail on this claim, a jury would need to find that Infuse "was *not* safe and effective" as labeled. *Gavin*, 2013 WL 3791612, at *15–16 (emphasis added); *Hafer*, 2015 WL 1648978, at *16 (same); *Caplinger*, 921 F. Supp. 2d at 1222 (same); *Lawrence v. Medtronic, Inc.*, 2013 WL 4008821, at *5 (Minn. Dist. Ct. 2013) (same). But that would conflict with the FDA's conclusive determination in granting premarket approval that "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318. Indeed, because the imposition of state-law liability for the alleged breach of a purported warranty as to the safety or effectiveness of medical device that has received premarket approval would effectively require that such a device be safer or more effective than demanded by the FDA, "[c]ourts have consistently found that state law claims for breach of warranties based on the safety or effectiveness of [such a] device, impose requirements 'that "are different from, or in addition to"' federal regulations, and thus are preempted." *Thomas v. Alcon Labs.*, 2013 WL 10888983, at *5 (N.D. Ga. 2013) (dismissing express-warranty claim as expressly preempted under § 360k(a)) (quoting *Riegel*, 552 U.S. at 330, in turn quoting 21 U.S.C. § 360k(a)).

That the purported warranty at issue in this case allegedly encompassed off-label uses is immaterial. When the FDA determined that Infuse is safe and effective as labeled, it knew that medical devices often are—and that Infuse in particular likely would

be (*cf.* Doc. 54, at 74–75)—used in an off-label manner. *See United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012) ("[T]he FDA's . . . approval process generally contemplates that approved [devices] will be used in off-label ways."). The express-warranty claim is therefore preempted. *See, e.g.*, *Gavin*, 2013 WL 3791612, at *15 (warranty claims involving off-label use of Infuse are preempted because they would finding "the Device was not safe and effective … contrary to the FDA's approval"); *accord Caplinger*, 921 F. Supp. 2d at 1222; *Wendt*, 2013 WL 3199361, at *1; *see also Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010); *Depuy Orthopaedics, Inc.*, 2013 WL 1108555, at *10.

Furthermore, Plaintiffs' breach of express warranty claim fails to articulate in any fashion what the express warranty made by Defendants was and how that express warranty could be enforced by Ohio law in a parallel fashion to federal law so as to avoid preemption. Plaintiffs' response cites *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901 (S.D. Ohio 2012), in support of their breach of express warranty claim. In *Hawkins*, the court allowed a claim of breach of implied warranty on a FDA Class III medical device to survive a motion to dismiss despite the plaintiff's failure to plead "the precise contours of [the plaintiff's] theory of recovery" because "it [was] clear from the allegations that [the plaintiff]'s claim is in fact premised upon the theory that Defendant violated federal law." *Id.* at 911.

This argument is without merit for two reasons. First, as explained in Part III.A, *supra*, this Court rejects the reduced pleading standard for products liability cases involving FDA Class III medical devices articulated in cases such as *Bausch*. Second,

Plaintiffs' express warranty claim in this case fails to meet even the more lax standard articulated by the court in *Hawkins*, as it is absolutely not "clear from the allegations that [the plaintiff]'s claim is in fact premised upon the theory that Defendant violated federal law." *Id.*

Accordingly, Plaintiffs' claim of breach of express warranty is preempted by 21 U.S.C. § 360k(a) and therefore warrants dismissal.

2. Implied Preemption

Defendants' motion to dismiss also argues that "[e]ven if Plaintiffs had stated a parallel claim that escapes express preemption under [21 U.S.C.] § 360k(a), any such claim predicated on alleged off-label promotion or an alleged failure to submit adverse-event reports to the FDA would be impliedly preempted[.]" (Doc. 61, at 63 (quoting *Cales*, 2014 WL 6600018)).

In enacting the FDCA, Congress not only declined to create a private cause of action, but also affirmatively required that any action to enforce the FDCA "shall be by and in the name of the United States" (21 U.S.C. § 337(a)), thereby mandating that the FDCA and its implementing regulations be "enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. Moreover, Congress granted the FDA "complete discretion" in deciding "how and when [its enforcement tools] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). That discretion is necessary "to achieve a somewhat delicate balance of statutory objectives," a balance that "can be skewed" if private tort suits are allowed. *Buckman*, 531 U.S. at 348. "This flexibility is a critical component of the statutory and regulatory framework under which the FDA

pursues difficult (and often competing) objectives." *Id*. at 349. Thus, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n.4.

Consequently, through 21 U.S.C. § 337(a), Congress impliedly preempted any private action seeking to enforce duties created by the FDCA and its implementing regulations. As the Sixth Circuit has explained, any claim that relies on the FDCA or its implementing regulations "'[a]s a critical element'" is barred by § 337(a). *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) (quoting *Buckman*, 531 U.S. at 353); *see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 936 (6th Cir. 2014) ("negligence claims" premised on "a violation of the FDCA" are impliedly preempted "because the FDA has the exclusive power to enforce the FDCA" and there is therefore "no private right to enforce the statute").[5]

Indeed, § 337(a) forbids private plaintiffs from asserting any "state claim [that] would not exist if the FDCA did not exist," or any claim for which "'the existence of [the] federal enactments is a critical element,'" because such a claim "is in substance (even if not in form) a claim for violating the FDCA" and may be enforced only by the federal government. *Riley*, 625 F. Supp. 2d at 777, 790 (quoting *Buckman*, 531 U.S. at 353); *see also Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at *7 (N.D. Ga. 2011).

[5] *See also Hafer*, 2015 WL 1648978, at *9 ("A plaintiff cannot bring a state-law claim that is in substance a claim to enforce the FDCA."); *Arnold v. Alphatec Spine, Inc.*, 2014 WL 2896838, at *6 (S.D. Ohio 2014) ("[C]laims for violations of the FDCA brought by private litigants are impliedly preempted"); *accord, e.g.*, *Caplinger*, 784 F.3d at 1339; *McClelland*, 944 F. Supp. 2d at 1200.

a. Claims Based on a Failure to Submit Adverse-Event Reports to the FDA are Impliedly Preempted

The Sixth Circuit has squarely held that claims premised on an alleged "failure to submit reports to the FDA" are impliedly preempted by § 337(a), as interpreted by *Buckman*, because any such claim would be an impermissible attempt to enforce exclusively federal requirements with no counterpart in state law. *Marsh*, 693 F.3d at 553.[6]

As *Buckman* teaches, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." 531 U.S. at 347; *see also Dawson v. Medtronic, Inc.*, 2013 WL 4048850, at *7 (D.S.C. 2013) ("[T]hese [reporting] regulations relate to information that manufacturers are required to provide to the FDA, and Plaintiff cannot usurp the FDA's regulatory oversight role for policing purported violations of the agency's regulations."). Any tort claim based on an alleged failure to submit adverse-event reports to the FDA "would not be relying on traditional state tort law which had predated" the FDCA (*Buckman*, 531 U.S. at 353), because no duty to

[6] *Accord Cupek*, 405 F.3d at 423–24 (claim that manufacturer failed to comply with the FDA's "conditions of approval," which incorporate the FDCA's reporting requirements, "is a disguised fraud on the FDA claim" preempted by *Buckman*); *see also, e.g., Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (claim that manufacturer was negligent for "not timely fil[ing] adverse-event reports, as required by federal regulations" impliedly preempted as "simply an attempt by private parties to enforce the MDA"); *Hafer*, 2015 WL 1648978, at *13 (claims based upon "failure to file adverse-event reports with the FDA . . . [are] impliedly preempted under *Buckman*"); *Byrnes*, 60 F. Supp. 3d at 1297 ("[T]o the extent that the claim is based on [an alleged] failure to report adverse events to the FDA, it is impliedly preempted"); *McClelland*, 2012 WL 5077401, at *7 ("[C]laims based upon FDCA disclosure requirements . . . are … impliedly preempted"); *Cales*, 2014 WL 6600018, at *10 (failure-to-warn claim "predicated on . . . an alleged failure to submit adverse-event reports to the FDA would be impliedly preempted under *Buckman* and 21 U.S.C. § 337(a)") (quotation marks and alteration omitted).

submit reports to the FDA would exist absent the FDA and the FDCA. Since "the existence of these federal enactments" is therefore "a critical element" of any such claims, those claims are impliedly preempted. *Id.*

Plaintiff's failure to warn claim, negligence claim, and products liability (misrepresentation) claim all rely upon Defendants' alleged failure to report adverse events to the FDA. Therefore, these claims are all impliedly preempted and warrant dismissal.

b. Claims Based on "Off-label Promotion" are Impliedly Preempted

"[T]here is no state-law duty to abstain from off-label promotion." *Thorn*, 81 F. Supp. 3d at 628; *accord, e.g.*, *Martin*, 32 F. Supp. 3d at 1045; *Beavers-Gabriel*, 15 F. Supp. 3d at 1041. Indeed, the very *concept* of off-label promotion did not exist—and could not exist—until Congress enacted the MDA and required that manufacturers obtain FDA approval of devices and their labels. *See Caplinger*, 921 F. Supp. 2d at 1219–20, 1224 ("[T]he concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of [state] law.").[7] Thus, the distinction between on-label and off-label use—and, hence, between on-label and off-label promotion—exists only by virtue of the federal regulatory scheme.

[7] *See also Gavin*, 2013 WL 3791612, at *17 ("[T]he very concept of 'off-label' use and promotion is derived from the regulatory system imposed by the MDA and the FDCA."); *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 398378, at *5 (E.D.N.Y. 2008) ("[T]here is no state-law equivalent of 'off-label.' The concept is entirely federal."); *accord, e.g.*, *Hafer*, 2015 WL 1648978, at *9; *Blankenship*, 6 F. Supp. 3d at 990; *Hawkins*, 2014 WL 346622, at *19.

Claims predicated on off-label promotion are thus "impliedly preempted under *Buckman* and § 337(a)," *Caplinger*, 921 F. Supp. 2d at 1219, "because promoting the off-label use of an FDA-approved medical device is not unlawful under 'traditional state tort law'" and any claim based on off-label promotion "would be in substance a claim for violating the FDCA." *Dawson*, 2013 WL 4048850, at *6 (quoting *Buckman*, 531 U.S. at 353).[8] Section 337(a) bars private enforcement of such claims because those claims would "usurp the FDA's regulatory oversight role for policing purported violations of" the statutes and regulations it has exclusive authority to administer. *Dawson*, 2013 WL 4048850, at *7.

Plaintiffs' failure to warn, design defect, negligence, and breach of implied warranty claims all rely on Defendants' alleged off-label promotion of Infuse. Accordingly, those claims are impliedly preempted and warrant dismissal.

C. Alternative Grounds for Dismissing Plaintiffs' Liability Claims

In addition to arguments based on preemption by the MDA, Defendants also advance several alternative arguments as to why Plaintiffs' product liability claims should fail. As this Court has held Plaintiffs' product liability claims to be preempted,

[8] *Accord Hafer*, 2015 WL 1648978, at *9 (given 21 U.S.C. § 337(a), "[a]ny claim based solely on off-label promotion would . . . be impliedly preempted"); *Blankenship*, 6 F. Supp. 3d at 990 (holding that claims based on alleged off-label promotion impliedly preempted because they are "not based on conduct that would give rise to a recovery under state law . . . in the absence of the FDCA"); *Evans v. Rich*, 2014 WL 2535221, at *2 (E.D.N.C. 2014) (off-label promotion "claim is impliedly preempted as it exists solely by virtue of the requirements of the FDCA"); *Thorn*, 2015 WL 328885, at *10; *Arthur v. Medtronic, Inc.*, 2014 WL 3894365, at *6–7 (E.D. Mo. 2014); *Brady*, 2014 WL 1377830, at *8; *Martin*, 32 F. Supp. 3d at 1045; *Beavers-Gabriel*, 15 F. Supp. 3d at 1041; *Dawson*, 2013 WL 4048850, at *6; *Gavin*, 2013 WL 3791612, at *17; *Houston*, 957 F. Supp. 2d at 1177–78; *Lawrence*, 2013 WL 4008821, at *4.

the Court need not rule upon these arguments. However, in the interest of completeness, the Court will address certain additional grounds for dismissal of Plaintiffs' claims.

1) Ohio Product Liability Act

Defendant claims that Plaintiff's product liability claims are preempted by the Ohio Product Liability Act (OPLA). Ohio Rev. Code Ann. §§ 2307.71 *et seq.* The OPLA established in Ohio a comprehensive statutory scheme governing product liability claims. As part of this scheme, the Act expressly states that it is intended "to abrogate all common-law product liability claims or causes of action." O.R.C. § 2307.71(B). Therefore, any product liability claim not brought under the OPLA would be subject to dismissal.

Plaintiffs did not adequately plead their claims under the OPLA. The OPLA is cited only once in the Omnibus Complaint, in the section establishing jurisdiction:

> The Ohio Product Liability Act (R.C. §§2307.71, *et. seq*.) does not impose requirements that are different from or in addition to those imposed by the federal Food and Drug Administration (hereafter the "**FDA**"), the Medical Device Amendments and Combination Drug and Device Amendments, the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq*., and the regulations promulgated thereunder at 21 CFR § 800, *et seq*. or elsewhere.

(Doc. 54, at 73). There is no citation to, or even mention of, the Act in any of the sections of the Omnibus Complaint outlining the claims against Defendants. These claims are all clearly pleaded as common-law causes of action arising from the design, production, or marketing of Infuse, or the warnings associated with Infuse, or the alleged failure of the Infuse device to conform to purported representations or warranties. These claims are therefore preempted by the OPLA.

Plaintiffs argue that the fact that their Omnibus Complaint failed to plead any claim under the OPLA is immaterial, citing the Seventh Circuit in *Bausch* for the proposition that a relaxed pleading standard is required in products liability cases involving medical devices. (Doc. 63, at 26). However, as explained in Part III.A, *supra*, this Court finds that Plaintiffs' complaint must be held to the traditional pleading standards of Rule 8 of the Federal Rules of Civil Procedure. Plaintiffs' failure to identify any specific statutory basis for their claims will not save them from dismissal.

Accordingly, Plaintiffs' products liability claims are abrogated by the Ohio Product Liability Act.

2) Comment K to Section 402A of the Restatement (Second) of Torts

Ohio has adopted Section 402A of the Restatement (Second) of Torts, according to *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 752 (Ohio 1988). That section provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> > (a) the seller is engaged in the business of selling such a product, and
> > (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in subsection (1) applies although
>
> > (a) the seller has exercised all possible care in the preparation and sale of his product, and
> > (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller."

However, Comment K to Section 402A provides an exemption to strict liability of manufacturers for injuries caused by defective products for "unavoidably unsafe" products. Specifically, the comment provides:

> "*Unavoidably unsafe products.* There are some products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." (Emphasis *sic*.) 2 Restatement of the Law 2d, Torts, *supra*, at 353-354.

White, 533 N.E.2d at 752. Therefore, Plaintiffs in this case cannot bring any state-law products liability claims against Defendants if Infuse is an "unavoidably unsafe" product.

Plaintiffs argue that "the determination as to whether any particular medical device is 'unavoidably unsafe' is necessarily made on a case by case basis," and that dismissal at this stage based on the Restatement is therefore inappropriate. (Doc. 63, at 36). Defendants argues in response that Infuse's classification by the FDA as a Class III

medical device inherently means that it is unavoidably unsafe and that Comment K's prohibition of strict liability claims therefore applies. (Doc. 65, at 49–50).

Defendant's argument is well taken. Class III devices such as Infuse are, as relevant here, defined as devices that are "for a use which is of substantial importance in preventing impairment of human health, or . . . present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). That Infuse in particular "presents a potential unreasonable risk of illness or injury" is evidenced by the fact that the FDA has both: (1) designated Infuse a "restricted device" given "its potentiality for harmful effect" (*id*. § 360j(e); Mem. Ex. 1 at 1 (designating Infuse a restricted device pursuant to 21 U.S.C. § 360e(d)(1)(B)(ii)) and (2) categorically determined that the less stringent regulatory controls applicable to Class II devices "are insufficient to provide reasonable assurance of safety and effectiveness for an intervertebral body fusion device when it contains a therapeutic biologic grafting material," as Infuse does. *See* Orthopedic Devices; Reclassification of the Intervertebral Body Fusion Device, 72 Fed. Reg. 32,170, 32,171 (June 12, 2007); *see also* 21 C.F.R. § 888.3080(b)(2) (classifying "intervertebral body fusion devices that include any therapeutic biologic (*e.g.*, bone morphogenic protein)" as Class III devices).

Plaintiffs suggest that it would be "inappropriate to determine at this juncture whether, for the Infuse device, 'there existed no alternative design which would have as effectively accomplished the same purpose or result with less risk,' such that the device can necessarily be said to be 'unavoidably unsafe' under Comment k." (Doc. 63, at 37 (quoting *White,* 533 N.E.2d at 753 (Ohio 1988)). Yet there is no alternative design for

Infuse that could lawfully be marketed. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications . . . that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). There is therefore no basis for "an in-depth evidentiary inquiry into alternative designs." (Doc. 63, at 39).

Plaintiffs also contend that Comment K does not apply to Infuse because the warnings that Medtronic provided were purportedly inadequate. Opp. 37 ("[P]roper warnings were not properly given."). But this argument also runs headlong into the device's receipt of premarket approval and the FDA's conclusive determination that the warnings contained in the Infuse label are adequate. *See Riegel*, 552 U.S. at 319 ("Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in … labeling … that would affect safety or effectiveness.") (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

Accordingly, Plaintiffs' strict liability claims are barred by Ohio's adoption of Section 402A of the Restatement (Second) of Torts due to the fact that Infuse is an "unavoidably unsafe product."

3) Medtronic expressly disclaimed all warranties

Defendants' motion to dismiss argues that Plaintiffs' claims for breach of express and implied warranties must fail because the FDA-approved labeling for Infuse states that "[n]o warranties, express or implied are made" and that "[i]mplied warranties of merchantability and fitness for a particular purpose or use are specifically excluded."

(Doc. 61-2, at 4). Defendant argues that this explicit disclaimer of warranties defeats Plaintiffs' warranty claims.

Plaintiffs do not argue that Defendant did not disclaim all warranties. Instead, Plaintiffs' response argues that "[Medtronic] may or may not have disclaimed warranties. However, since this subject was not mentioned within the Complaint, the topic of disclaimers is not proper in the context of a motion to dismiss." (Doc. 63, at 33).

Plaintiffs' argument is not well taken. This Court may take judicial notice of Infuse's receipt of PMA from the FDA, including the device's FDA-mandated warning label which includes the warranty disclaimers. *See, e.g., Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013) (taking judicial notice of FDA-approved drug label published on FDA website).[9] Moreover, "[t]aking judicial notice of matters of public record need not convert a motion to dismiss into a motion for summary judgment." *Ennega v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012). This Court may therefore consider the FDA-approved label of the Infuse device in determining whether Defendants have effectively disclaimed all warranties. And here, Defendants have in fact done so.

Plaintiffs also argue that, even if Defendants disclaimed all warranties, an express warranty from Defendants overrides any warranty disclaimer. (Doc. 63, at 33 (citing *Scovil v. Medtronic, Inc.*, 2015 WL 880614 (D. Nev. 2015)). However, as explained in

[9] *See also Gross*, 858 F. Supp. 2d at 481 n.26 (taking judicial notice of Summary of Safety and Effectiveness Data); *White v. Striker Corp.*, 818 F. Supp. 2d 1032, 1034–36 (W.D. Ky. 2011) (taking judicial notice of Summary of Safety and Effectiveness Data); *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1023–24 (C.D. Cal. 2008) (taking judicial notice of drug labels posted on FDA website).

Part III.B.1.b.3, *supra*, Plaintiffs have failed to adequately allege any express warranty made by Defendants.

Accordingly, Defendants' explicit disclaimer of all warranties defeats Plaintiffs' breach of express and implied warranty claims.

D. Fraud Claims

Unlike Plaintiffs' other claims, the fraud claims in the Omnibus Complaint are not implicated by any preemption analysis. While the other claims all would require some finding that either the Infuse product itself or the Infuse labeling imposed by the FDA were legally deficient in some way, Plaintiffs' fraud claim is solely related to actions allegedly taken by Defendants—*i.e.*,affirmative misrepresentations about the safety or effectiveness of Infuse and its off-label use—wholly separate from their manufacturing or labeling of Infuse.

Plaintiffs' fraud claims are subject to the heightened pleading standard outlined in Federal Rule of Civil Procedure 9. That rule states in relevant part:

> (b) Fraud or Mistake; Conditions of Mind. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

Fed. R. Civ. P. 9(b). The Sixth Circuit has held that Rule 9(b) specifically requires a claim of fraud to "allege the time, place, and content of the alleged misrepresentations on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Sanderson v. HCA—The Healthcare Co. et al.*, 447

F.3d 873, 877 (6th Cir. 2006) (quoting *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 563 (6th Cir. 2003)).

Defendants have identified several portions of Plaintiffs' fraud claim that fail to meet the Rule 9(b) pleading standard. The most glaring flaw in Plaintiffs' fraud claim is that it simultaneously alleges two contradictory sets of facts. On the one hand, Plaintiffs allege that they were defrauded by Dr. Durrani—who Plaintiffs allege was acting as an agent for Medtronic—when he allegedly misled Plaintiffs concerning the safety of Infuse. On this theory, "Dr. Durrani was an Opinion Leader for Defendants" (Doc. 54, at 127) and as such had purportedly "known . . . for many years" that "off-label use of Infuse in the spine frequently causes serious adverse events" (*Id.* at 94), yet not only "conceal[ed] these risks from the Plaintiffs" (*Id.* at 163) but also "fraudulently and intentionally misrepresented" them to Plaintiffs (*Id.* at 793). On the other hand, Plaintiffs allege that Medtronic "misrepresented the safety of Infuse to . . . Dr. Durrani." *Id.* at 82. On this theory, under which Medtronic supposedly "did not adequately inform . . . Dr. Durrani . . . of the true incidence of dangerous side effects resulting from the use of Infuse in off-label surgeries or . . . in any surgery, whether off-label or otherwise" (*Id.* at 163), Dr. Durrani was purportedly "justified in relying . . . on Defendants' concealment of information and misrepresentations about the safety risks related to Infuse in deciding to make off-label use of Infuse for spine surgery" (*Id.* at 797). Thus, Plaintiffs allege that Dr. Durrani simultaneously had and did not have knowledge of the true facts regarding the safety of Infuse.

The inconsistent factual statements of the Omnibus Complaint are not saved by the Federal Rules of Civil Procedure's allowance of alternative pleading. While Rule 8(d)(3) allows inconsistent claims—a plaintiff may, for example, bring claims for both intentional and unintentional torts, even where recovery on both would impossible—it does not allow what Plaintiffs are attempting to do here—namely, to make "clashing factual assertions . . . in the context of the same claim." *Nat'l W. Life Ins. Co. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 175 F. Supp. 2d 489, 492 (S.D.N.Y. 2000) (emphasis added) (dismissing fraud claim where plaintiff made contradictory factual allegations as to knowledge).

The distinction between inconsistent claims, which are permissible, and inconsistent factual allegations in support of a single claim, which are not, "is especially pertinent in cases alleging fraud." *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 406–07 (S.D.N.Y. 2001); *cf. Merchant v. Davies*, 244 F.2d 347, 348 (D.C. Cir. 1957) (Rule 8(d)(3) "creates no exception to the principle that a charge of fraud must be clear and specific."). Here, whether Plaintiffs claim that they were defrauded by Dr. Durrani acting as Medtronic's agent or claim that Dr. Durrani was defrauded by Medtronic, Plaintiffs' fraud-based claims against Medtronic necessarily depend on what Dr. Durrani knew about the risks associated with Infuse. Yet Plaintiffs simultaneously allege that Dr. Durrani both did, and did not, have knowledge of those risks. These contradictory factual allegations made in support of the same fraud-based claims defeat those claims.

Accordingly, Plaintiffs' claim of fraudulent concealment, misrepresentation and fraud in the inducement warrants dismissal.

IV. CONCLUSION

Ultimately, with the exception of Plaintiffs' fraud-based claims, all of the claims raised in the Omnibus Complaint represent an attempt to use state law to violate the regulatory monopoly on medical devices which was granted to the FDA via 21 U.S.C. § 360(k). This Court therefore finds, as have many of the other courts across the country that have considered these exact issues, that product liability claims of this nature cannot survive a motion to dismiss. Plaintiffs' fraud claims independently fail for failing to meet the heightened pleading standard of Rule 9 of the Federal Rules of Civil Procedure.

Accordingly, **IT IS ORDERED** as follows:

1) Defendants' motion to dismiss (Doc. 61) is **GRANTED**;

2) The Clerk shall enter judgment in each of the consolidated cases accordingly, whereupon those cases are **TERMINATED** on the docket of this Court.

Date: 9/22/16

s/ Timothy S. Black
Timothy S. Black
United States District Judge